

Attorney Docket No. P65141US0
Application No. 09/508,095

Remarks/Arguments:

Claims 30-33, 36, 37, 40, 41, 44, and 45 are pending.

Claims 34, 35, 38, 39, 42, and 43 are canceled, hereby, without prejudice or disclaimer.

Pending claims 30, 40, and 41 are amended, hereby. Pending claims 31-33, 36, 37, 44, and 45 were previously presented.

Claims 30 and 41 are amended by canceling, without prejudice or disclaimer, the "fragments" subject matter. Claims 30 and 40 are, further, amended to more clearly define the instant invention by deleting the word "derivatives" and by specifying that the claimed "peptide" includes each of the expressly recited sequences "N-modified by amidation, acetylation, sulfation, phosphorylation, glycosylation, or oxidation." Additionally, each of claims 30, 40, and 41 is amended to more clearly define the invention by defining the claimed "peptide" as "an amino acid sequence," selected from among a group of expressly recited sequences, or "the *amino acid sequence* N-modified by amidation, acetylation, sulfation, phosphorylation, glycosylation, or oxidation" or further, with respect to claim 30 only, "a fusion protein, thereof, obtained by chemical bonding."

In view of the instant amendment, the claim objections and rejections of record as applied to any of the claims canceled, hereby, are rendered moot.

Claims were objected to for including non-elected species of amino acid sequences (SEQ ID NOS). The objection is traversed in that restriction/election practice cannot be used to sub-divide a proper generic claim. It is well established that a claim cannot be subject to Restriction under §121 merely because allegedly independent and distinct inventions fall within the generic scope of the

Attorney Docket No. P65141US0
Application No. 09/508,095

claim. *In re Weber*, 198 USPQ 328-332 (CCPA 1978). *In re Haas* ("Haas I"), 179 USPQ 623 (CCPA 1973).

The matter at issue concerns restriction practice involving markush-type claims. As such, the restriction is improper where there exists unity of invention. MPEP 803.02. The only amino acid sequences having a sequence identifier found in present claims 30-34, 41, and 45 are those selected from the Markush group

- a) R_1 -EVAARARVW- R_2 (SEQ ID NO: 8),
- b) R_1 -ARRARVVWAAVG- R_2 (SEQ ID NO: 22),
- c) R_1 -ARRARVVWCAVG- R_2 (SEQ ID NO: 14), and
 R_3 -CIAL- R_4 (SEQ ID NO: 15)
- d) R_1 -ARRARVVWCAVGE- R_2 (SEQ ID NO: 16),
 R_3 -CIAL- R_4 (SEQ ID NO: 15)

Present claims 40 and 44 contain the same Markush group plus additional group members

R_1 -YQRRPAIAINNPYVPRTYYANPAVVRPHAQIPQOYLPNSHPPTVVRPNLHPSF- R_2 (SEQ ID NO: 17), excluding amino acid sequence 1-62 of human K-casein, and

R_1 -GRRRSVQWCAVSQPEATKCFQWQRMNRKVRGPPVSCIKRDSPIQCIQA- R_2

 (SEQ ID NO: 19).

SEQ ID NOS 17, 19, and 22 were examined pursuant to restriction.

Among the members of Markush group a)-d), and SEQ ID NOS 8, 22, 14, and 16, striking similarity is readily apparent with respect to an 8-amino-acid residue found in each of the members, i.e.,

Attorney Docket No. P65141US0
Application No. 09/508,095

- a) -AARARVVW- (amino acids 2-9 in SEQ ID NO: 8)
- b) -ARRARVVW- (amino acids 2-9 in SEQ ID NO: 22)
- c) -ARRARVVW- (amino acids 2-9 in SEQ ID NO: 14)
- d) -ARRARVVW- (amino acids 2-9 in SEQ ID NO: 16)

The 8-amino-acid residue in each of members b)-d), and in each of SEQ ID NOS 22, 14, and 16, is identical, and 8-amino-acid residue in a), and in SEQ ID NO: 8, varies by only a single amino acid, i.e., 'A' instead of 'R' as the 2nd amino acid in the sequence.

The aforesaid similarity effects a structural feature common to each of the members of Markush group a)-d), and each of SEQ ID NOS 8, 22, 14, and 16. Since all the group members share a property in common – each is *bifidogenic* – unity of invention exists for the Markush group a)-d), and for SEQ ID NOS 8, 22, 14, and 16, which include elected SEQ ID NO: 22, exists and, so, restriction among Markush group a)-d), and among and SEQ ID NOS 8, 22, 14, and 16, is improper. *In re Harnish*, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

The rejection under 35 USC 112, first paragraph, for alleged lack of enablement, as applied against the pending claims, is overcome by the instant amendment. Specifically, by canceling "fragments" from the claims, the reasons for the rejection based on the "fragments" subject matter are rendered moot. Moreover, one of ordinary skill in the art would readily appreciate that *N-modification* of the sequences expressly recited in the pending, rejected claims would be enabled as to their use, that is, the N-modified sequences would be useful for their intended purpose as described in the subject application. This is because, as well-known by one skilled in the art, the

Attorney Docket No. P65141US0
Application No. 09/508,095

type of N-modification recited in the present claims would ordinarily not be expected to completely destroy properties possessed by the non-N-modified sequences.

Additionally, lack of enablement under §112 is not established by mere allegations of undue breadth, that is, by merely arguing that claims read on non-disclosed embodiments. *Horton v. Stevens*, 7 USPQ2d 1245 (BPA & I 1988).

Accordingly, withdrawal of the rejection under 35 USC 112, first paragraph, for alleged lack of enablement appears to be in order.

The rejection under 35 USC 112, first paragraph, for allegedly claiming subject matter not found in the application as originally filed ("the new matter rejection") is not applicable against the claims as presently amended and, therefore, appears to be in order for withdrawal.

According to the statement of rejection, the rejection is made because the subject application "has not identified" a list of specifically mentioned embodiments, which fall within the scope of the claims. However, that the claims read on non-disclosed embodiments is insufficient reason and, so, fails to justify a new-matter rejection. In order to satisfy the requirements of §112, first paragraph, "it is not necessary to embrace in the claims or describe in the specification all possible forms in which the claimed principle may be reduced to practice." *Smith v. Snow*, 294 U.S. 1, 11 (1935). The law does not require an applicant to describe in his specification every conceivable embodiment of the invention. *SRI Int'l v. Matsushita Elec. Corp. of America*, 227 USPQ 577, 586 (Fed. Cir. 1985). Moreover, while working examples drawn to specific embodiments may be desirable, they are not required in order to satisfy enablement under §112. *In re Strahilevitz*, 212 USPQ 561 (CCPA 1982).

Attorney Docket No. P65141US0
Application No. 09/508,095

The pending claims were rejected under 35 USC 112, second paragraph, for allegedly being indefinite. The rejection is poorly taken and, accordingly, appears to be in order for withdrawal.

First of all, the statement of rejection relies on the claims supposedly reciting such phrases as "for example" and "such as." Contrary to the statement of rejection, such phrases do not appear in the claims *as rejected*, i.e., the claims pending prior to the instant Office Action.

Further, the statement of rejection alleges that the sequences that are *N-modified* in accordance with the present claims are indefinite because, allegedly, it "is unclear what amino acid sequence is amidated, acetylated, sulfated, phosphorylated, glycosylated, and oxidized as to thereof." This reasoning reflects concern about the *scope* of the language at issue, which has no bearing on whether the term is indefinite under §112, ¶2, since claim "breadth is not to be equated with indefiniteness." *In re Miller*, 169 USPQ 597, 600 (CCPA 1970). Although an "undoubtedly large number" of embodiments might fall within the scope of a generic expression "the expression is not for that reason indefinite," *In re Skoll*, 187 USPQ 481, 482 (CCPA 1975), and whether a particular embodiment is covered by the expression "is rendered no less certain by the large number." 187 USPQ at 483.

Additionally, claim 40 is amended, hereby, to use the terminology as kindly suggested by the Examiner in the prior Office Action.

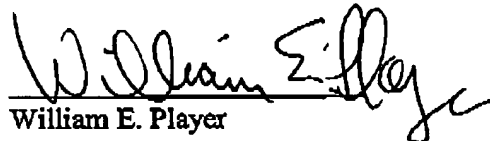
Attorney Docket No. P65141US0
Application No. 09/508,095

Favorable action is requested.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By


William E. Player
Reg. No. 31,409

400 Seventh Street, NW
The Jenifer Building
Washington, D.C. 20004
Tel. (202) 638-6666
Fax (202) 393-5350
Date: August 18, 2004
WEP/id
R:\Homer\thomas\2004\AUGUST\P65141 af and.wpd